

The pharmaceutical robot Dosell receives MDR marking from the Medical Products Agency

Stockholm, Sweden. iZafe Group AB (publ.) (NASDAQ First North: IZAFE B) – a leading life science company in the digitalization of medication management announces today that the company's pharmaceutical robot Dosell has been registered in the Medical Products Agency and certified under MDR. This means that the product is approved in accordance with the EU regulation on medical devices that ensures the safety and performance of medical devices.

With registration in the Medical Products Agency and certification under MDR, iZafe Group's pharmaceutical robot Dosell meets the requirements of the new regulation.

Dosell has been CE marked according to previously applicable directives for medical devices, MDD. The new EU Medical Device Regulation (MDR) replaced the MDD in May 2021. Like all medical device companies with products on the European market, iZafe Group has had to adapt its operations to meet the new requirements for CE marking of the products.

"Our pharmaceutical robot Dosell has been registered with the Medical Products Agency and certified under MDR. The MDR certification is important because it certifies that the product continues to meet the EU's essential health, safety, and environmental requirements. We have invested both time and financial resources to ensure that we comply with all new directives, and we are proud that we succeeded in submitting the application on May 26, when MDR replaced MDD." says Anders Segerström, CEO of iZafe Group.

About the EU regulation

The regulation updates the rules on which medical devices may be on the market, and how products are provided and used. The regulation improves patient safety by introducing stricter methods for assessment and monitoring in the market. It also contains rules for how medical technology companies conduct product evaluations within the EU. This ensures that unsafe and incompatible products and equipment do not end up on the market.

For more information [click here](#).

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About Us

iZafe Group is a Swedish med-tech company that develops and markets medical and digital security solutions to create safer drug handling at home. Our digital medicine dispenser Dosell reduces the risk of incorrect medication, increases security for family and relatives and relieves public care personnel. Our products form a holistic concept that facilitates patient medication and gives those who are treated at home better conditions for a happy and safe life.

The company is listed on the NASDAQ First North Premier Growth Market. FNCA Sweden AB is the company's Certified Adviser. Phone: +46 (0) 8 528 00 399. E-mail: info@fnca.se. Further information is available at www.izafegroup.com/investor-relations.

Attachments

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